SEP 1 9 2000

K002735

SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor: Biomet, Inc.

Manufacturer: Biomet Manufacturing, Corp.
56 East Bell Drive
Warsaw, Indiana 46582

Proprietary Name: Ascent™XXL Open Box Femoral Component

Common or Usual Name: femoral knee component

Classification Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (CFR 888.3560)

Device Classification: Class II

Device Product Code: 888.3560

Device Description: The Ascent™XXL Open Box Femoral Component is indicated for the relief of pain and restoration of motion due to non-inflammatory degenerative joint disease, rheumatoid arthritis, deformities of the knee, and revision of previously failed knee replacements. This device is intended for use with bone cement.

The Ascent™XXL Open Box Femoral Component is designed for use in cases where extensive ligament damage has occurred.

The Open Box Femoral Component is available in XXL, which is an addition to the previous five sizes. The anatomic component design allows the surgeon to reconstruct the anatomic dimensions and kinematics of the natural femur.

The femoral component may be used with either a constrained or PS tibial bearing. The term "constrained" tibial bearing is used to show that there is some constraint in varus/valgus and axial rotation between femoral and tibial components but there is no linkage of the components.

The Ascent™XXL Open Box Femoral Component also has independent posterior and distal augments to correct bone loss deficiences.

Indications for Use: The indications for use of the Ascent™Knee are the same as for other conventional knee prostheses. These include the relief of pain and restoration of motion due to non-inflammatory degenerative joint diseases, rheumatoid arthritis, deformities of the knee, and revisions of previously failed knee replacements.

Potential Risks: The potential risks associated with this device are the same as with any joint replacement device. These include, but are not limited to:

Reaction to bone cement	Blood vessel damage	Bone fracture
Deformity of the joint	Soft tissue imbalance	Infection
Cardiovascular disease	Delayed wound healing	Hematoma
Fracture of the cement	Metal sensitivity	Dislocation
Implant loosening/migration	Fracture of the components	Excessive Wear
Tissue growth failure	Nerve damage	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 9 2000

Ms. Michelle L. Mckinley
Biomet Orthopedics, Inc
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K002735
Trade Name: Ascent™ XXL Open Box Posterior Stabilized (PS) Femoral Component
Regulatory Class: II
Product Code: JWH
Dated: August 25, 2000
Received: September 01, 2000

Dear Ms. Mckinley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Diane R. Lochner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002735

Device Name: Ascent™XXL Open Box Femoral Component

Indications for Use:

The Ascent™XXL Open Box Femoral Component is indicated for:

1) Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved.
2) Correction of varus, valgus, or posttraumatic deformity.
3) Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

This device is intended for use with bone cement.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE OF ANOTHER PAGE IS NEEDED)

Donna R. Lochner

(Division Sign-Off)
Division of General Devices
510(k) Number K002735